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EXAMINER

KANTAMNENI, SHOBHA

ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,848

Applicant(s)

NIZARD ET AL.

Examiner

Shobha Kantamneni

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/03/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 94-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 94-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 94-113 are pending. The Amendment filed 11/03/2004, amended claim 105.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 12/03/2004 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 112, and 113 are rejected under 35 U.S.C. 112, second paragraph, as being vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 112 the recitation "wherein the lipid algal extract comprises from about 0.01 % to 10 % by weight of said lipid extract", and in claim 113 the recitation "wherein the lipid algal extract comprises from about 0.01 % to 3 % by weight of said lipid extract" is not clear. The claims 94, and 100 on which these claims depend teach only one type of lipid algal extract which is obtained by extracting the alga *Skeletonema* with alcoholic solvents. It is not clear what the difference is between lipid extract of alga *Skeletonema*, and lipid algal extract.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 94-97, 99-102, 108, 112, and 113 are rejected under 35

U.S.C. 102(b) as being anticipated by Briand (English Translation of FR 2,657,012).

The instant invention is directed toward a method for promoting intercellular communication of skin cells, comprising the application, to the appropriate skin areas of a person in need thereof, an effective amount of at least one lipid extract of the alga *Skeletonema*.

Briand teaches the use of microscopic algae extracts for the preparation of cosmetics, herein the extracts have free radical reducing activity, wherein a decrease in free radical production is established in the art to reduce aging, see page 2. *Skeletonema* is specifically taught as a preferred extract, see page 3. Briand further teaches the preparation of algae extracts wherein 100 g of *Skeletonema* in 180 l of water and 20 ml of isopropyl alcohol is mixed, ground, and extracted with slight stirring for 20 hrs at 30 °C. Glycol extract of *Skeletonema* is also disclosed. See page 6, lines 1-6; page 7, Example 12; page 15, line 7. The hydroalcoholic extracts of Briand will contain both lipid soluble components and polar solvent soluble components of algae *Skeletonema*. The cosmetics are taught as compositions comprising algae extracts and additional cosmetic ingredients/agents for treating and protecting the skin. See page 12.

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External application is specifically taught, see page 12. Exemplified is a composition comprising 3% glycol extract of *Skeletonema*. See page 15, line 7.

It is respectfully pointed out that Briand et al. is directed toward reducing free radical activity, wherein a decrease in free radical production is established in the art to reduce aging, see page 2, and the instant invention is directed to treating aging by promoting intercellular communication of skin cells. Thus, Briand et al. is directed to a person in need thereof (someone with aging skin) and appropriate skin areas, i.e. areas that need reduction of free radical activity. Since Briand et al. teach the extract in the amount recited by the instant claims and specification, Briand et al. teach an effective amount of the alga *Skeletonema*. Since a compound and its properties are inseparable, the hydroalcoholic extract of alga *Skeletonema* has the properties of promoting intercellular communication via gap junctions of keratinocytes, fibroblasts and skin preadipocytes and of promoting intercellular communication to promote the formation of connexin.

The claims are directed to a method of applying a composition comprising a lipid extract of *Skeletonema* to appropriate skin areas of a person in need thereof. Any properties exhibited by or benefits provided by the composition are inherent and are not given patentable weight over prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show

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that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which would inherently promote intercellular communication of skin cells, and promote the formation of connexin 43 as instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 98, 103-106, 109-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briand (English Translation of FR 2,657,012) as applied to claims 94-97, 99-102, 108, 112, and 113 in view of Winget (5,767,095).

The instant invention is directed toward a method for promoting intercellular communication of skin cells, comprising the application, to the appropriate skin areas of a person in need thereof, an effective amount of at least one lipid extract of the alga *Skeletonema*, wherein the lipid algal extract is obtained by liquid-liquid extraction.

Briand is as discussed above.

Briand does not teach the lipid algal extract as obtained by liquid-liquid extraction with an apolar solvent.

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Briand does not specifically teach the amounts of alcoholic solvents used for the extraction as between about 0.1 liter to 20 liters, per 100 g of alga.

Briand does not specifically teach that the extraction is performed under reflux.

Briand does not teach that the extraction is performed under an inert atmosphere.

Winget teaches anti-inflammatory compositions containing a purified microalgal lipid preparation for application to the skin. *Skeletonema* is specifically taught as a preferred algae. Such microalgal lipid extracts are taught as imparting potent anti-inflammatory effects to the skin of a user. See Col. 2, lines 37-40; Col. 10, lines 9-20. Winget further teaches microalgal lipid extract as obtained by liquid-liquid extraction. For example, the algal concentrates are extracted first with polar solvents such as alcohols, selected from a group consisting of methanol, ethanol, propanol, isopropanol, and acetone, wherein an extraction with 90 % aqueous ethanol is accomplished at a temperature near the boiling point. The filtrate obtained is then extracted using "organic water-immisible solvent". Non-polar organic solvents such as hydrocarbons, ethers, and chlorinated hydrocarbons are taught. See column 10, line 46-column 11, line 22. An EXAMPLE wherein the lipid extract was obtained by extracting an algal cake 1.5 kg with 4 L of boiling 90 percent aqueous ethanol is also taught. See column 14, lines 12-15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a lipid algal extract of *Skeletonema* obtained

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by liquid-liquid extraction into the compositions of Briand or to teach the extracts of Briand as liquid-liquid extraction components, as taught by Winget, because of the expectation of achieving a product that treats existing aging and protects again further skin aging by UV damage.

It would have been obvious to a person of ordinary skill in the art at the time of invention to perform the extraction under reflux because Winget teaches that the lipid extract is obtained by boiling with aqueous ethanol. One would be motivated to perform the extraction under reflux with the expectation of solubilizing the lipid components in the extraction medium and thus getting a better yield of the lipid extract.

It would have been obvious to a person of ordinary skill in the art to use alcoholic solvent in an amount between 0.1 liter to 20 liters per 100 g of alga because Winget teaches that the lipid extract is obtained by extraction with 1500 gms of algal cake with 4 L of ethanol. One would be motivated to perform the extraction with the specified amounts of the solvent of the instant invention with the expectation of increasing the solubility of the lipids and thus extracting all the lipid components from the alga *Skeletonema*.

It would have been obvious to a person of ordinary skill in the art to perform the extraction under an inert atmosphere (claims 110-111) to achieve a beneficial effect such as stability of the components of alga *Skeletonema*. It is respectfully pointed out that merely modifying the process conditions such as temperature, pressure, inert atmosphere etc. is not a patentable modification

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absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

The Examiner respectfully points out that the recitation "wherein the alga is frozen before being extracted" in instant claims 104, and 105 is a product-by-process limitation. Examiner respectfully points out the claims 98, and 106 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964 (Fed. Cir. 1985). See MPEP 2113. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Briand (English Translation of FR 2,657,012) as applied to claims 94-97, 99-102, 108, 112, and 113 in view of Friedrich (4,466,923).

Briand does not teach the lipid algal extract as obtained by extraction with supercritical CO₂.

Friedrich teaches the extraction of lipid-containing substances such as triglycerides with supercritical CO₂. It also disclosed that the solubility of the lipid in the supercritical CO₂ solvent can be increased by adjusting pressure and temperature. See column 2, lines 42-60. It is further taught that supercritical CO₂ is an ideal solvent for both the extraction and fraction of lipids because it is

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nontoxic, nonexplosive, cheap, easily removed from the extracted products. See column 1, lines 38-45.

It would have been obvious for a person of ordinary skill in the art to teach supercritical CO₂ as the extraction medium for the extracting lipids from the alga skeletonema because Friedrich teaches that lipids can be extracted using supercritical CO₂. One would be motivated to obtain lipid algal extract by extracting the alga skeletonema with supercritical CO₂ with the expectation of obtaining lipid extract of skeletonema which is free from toxic solvents.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 94-113 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,447,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are

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directed to a method of cosmetic care comprising application to the skin areas in need thereof, an effective amount of lipid extract of the algae *Skeletonema*. Thus both sets of claims are directed to a method of applying the same composition, comprising a lipid extract of the algae *skeletonema*. Therefore, if '782 art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Thus the composition of '782 inherently promotes intercellular communication of skin cells, as instant claims. Thus it would have been obvious to a person of ordinary skill in the art at the time of invention to teach a method for promoting intercellular communication of skin cells by applying lipid extract of alga *Skeletonema*. One would be motivated to use the composition comprising lipid extract of alga *skeletonema* with the expectation of treating physiological effects of skin ageing, such as wrinkles, loss of elasticity of the skin, etc.

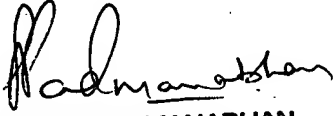
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on 8 am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
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